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MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/043,774	Applicant(s) SHARMA ET AL.	
	Examiner Terry A. McKelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,9-11 and 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-2, 4-8, and 12-13 in the paper filed 11/12/03 is acknowledged. Claim 3, which was incorrectly included in Group I in the previous communication, clearly belongs with Group III because it is drawn to the hiwi gene product and thus is not elected.

Claims 3, 9-11, and 14-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 11/12/03.

Claim Objections

Claim 2 is objected to because of the following informalities: There is an extra period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-8, and 12-13 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid comprising a nucleotide sequence encoding a human hiwi gene, including those that specifically encode SEQ ID NO:2, and said nucleic acid which hybridizes to SEQ ID NO:1. These nucleic acids read on cDNAs encoding hiwi (including allelic variations of hiwi protein), genomic DNAs which encode hiwi, and allelic variants of the nucleic acids. Thus, the claims are drawn to a genus of nucleic acids that is defined only by encoding hiwi and allelic variants of hiwi (which is defined by the specification as retaining the function of hiwi).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the

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genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the specification sets forth one single cDNA sequence (SEQ ID NO:1) encoding one single human hiwi protein (SEQ ID NO:2). There is no description of the structure of even one genomic DNA encoding hiwi. Thus, there is no description of the elements of the genomic DNA encoding human hiwi, such as the intron/exon structure, regulatory elements, and untranslated regions. There is no description of the structure of any allelic variants of hiwi cDNA, hiwi genomic DNA, or hiwi protein, and there is no description of the parts of the hiwi sequences which are conserved or vary between allelic variants. The art indicates that the structure of genes with intron/exons, naturally occurring regulatory regions, and untranslated regions is empirically determined because there is no known or disclosed correlation between the function (encoding a protein that has hiwi activity) and structure of the non-described hiwi nucleic acids. For example, the structural elements of a gene mediating the expression of a particular protein in the liver may be different than the structural elements of the gene mediating the

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expression of the same protein in the brain. Therefore, the structure of these elements and the sequences which are conserved between allelic variants are not conventional in the art.

Accordingly, weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art, given the absence in the specification of sufficient recitation of distinguishing characteristics of genomic DNA encoding hiwi, and allelic variants of hiwi sequences, would not recognize from the disclosure that the applicant was in possession of the genus of nucleic acids that encompasses hiwi genomic DNAs and allelic variants of hiwi sequences. Therefore, the specification does not provide adequate written description of the claimed genus which encompasses the second type of inhibitor.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision

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the detailed chemical structure of the encompassed genus of nucleic acids encoding hiwi, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a cDNA comprising SEQ ID NO:1 or encoding SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

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"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-2, 4, and 12-13 are rejected under 35 U.S.C. § 101 because the claimed invention is drawn to non-statutory subject matter.

The preamble of the claims recites "A nucleic acid ..." and "A nucleic acid hybridization probe ...". Nucleic acids (which reads on non-isolated natural nucleic acids in cells) and nucleic acid hybridization probes (which reads on natural nucleic acids such as mRNAs) are products of nature that are not statutory subject matter because they fail to show the "hand of man" in their construction. Amending the claims to recite "An isolated DNA nucleic acid ..." or "An isolated nucleic acid hybridization probe ..." would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-8, and 12-13 are rejected under 35

U.S.C. 102(a) as being anticipated by Sharma et al.

Sharma et al teach an nucleic acid that 100% matches SEQ ID NO:1 (and thus would hybridize to SEQ ID NO:1 under hybridization conditions), that comprises a nucleotide sequence which encodes hiwi of SEQ ID NO:2 (pages 427-428). See the attached sequence comparison. A recombinant expression vector comprising a nucleotide sequence encoding hiwi, and the vector in a cell culture, is taught (page 428).

Claims 1, 5, 7, and 12-13 are rejected under 35

U.S.C. 102(b) as being anticipated by Lin (WO 00/32039).

Lin et al teach an isolated nucleic acid (SEQ ID NO:5 in the reference) which comprises a nucleotide sequence encoding human piwi, designated human hiwi (pages 5-6; page 10; claim 14). See the attached sequence comparison. A recombinant expression vector comprising the nucleic acid is taught (claim 23). A cell culture transformed with a recombinant expression vector expressing human hiwi is also taught (claims 26 and 29). Because of the high degree of similarity, the nucleic acid taught by the reference would hybridize to SEQ ID NO:1.

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Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213 until January 14, 2004, and (571) 272-0775 after January 14, 2004. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

December 13, 2003